

REMARKS

In view of the following remarks, the Examiner is requested to allow claims 1, 2, 6-9, 11, 31-41, 43-45, as well as newly presented Claims 46-47, the only claims pending and under examination in this application.

As an initial matter the Applicants would like to thank the Examiner for removing the finality of the previous Office Action.

Claims 46 and 47 have been added. These claims find support in the specification at page 6, line 11 to page 7, line 30. As these claims introduce no new matter, their entry by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1-2, 6-9, 11, 31-34, 36-41 and 43-45 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Sproul (USPN 6,832,988).

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 1, 11 and 36 are directed to methods for introducing a flowable orthopedic calcium phosphate cement composition to a target bone site.

An element of the methods is delivering a flowable cement composition to a target bone site by the application of vibration in a manner such that the penetration of

the cement into the target bone site stops simultaneously with the cessation of vibration.

The Applicants contend that the combination of Constantz and Sproul does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops simultaneously with the cessation of vibration. This element of the claimed invention is important, as it allows one to use both high viscosity and low viscosity cements and provides high control over their delivery and therefore reduces risk of the occurrence of emboli.

In rendering this rejection, the Office asserts that because Constantz discloses the use of vibration in conjunction with the delivery of cement into a cancellous region, Constantz necessarily teaches that when vibration is stopped infiltration is also "simultaneously stopped."

The Office, however, has cited no support for its position that when vibration is stopped infiltration of the cement into the bone necessarily and simultaneously stops. The Office, therefore, is assuming that it is an inherent characteristic of the methods disclosed in Constantz that when the driving force for the cement delivery is removed the flow of cement ceases simultaneously with the cessation of the driving force. The Applicants respectfully disagree.

According to the M.P.E.P. § 2112, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Rather, to establish inherency, "the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Accordingly, in relying upon the theory of inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that

the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

The Applicants contend that the Office has not provided any basis in fact or technical reasoning that supports the determination that when the driving force for the cement delivery is removed the flow of cement necessarily ceases simultaneously with the cessation of the driving force.

In fact, simply removing the initial impulse of a flow to thixotropic compositions like calcium phosphate cements does not necessarily mean that when that impulse is removed the flow will automatically stop.

As is known in the art, thixotropic fluids are those fluids that change their viscosity due to agitation, such as vibration. The change in viscosity of a thixotropic fluid is time dependent. Therefore, the longer the fluid is under a shear force the less viscous it becomes. The less viscous the fluid becomes the greater will be its rate of flow.

Hence, because the change in viscosity of a thixotropic fluid is time dependent, removal of the shear force does not mean that the fluid instantaneously becomes so viscous that its flow simultaneously ceases with the cessation of the applied force. Rather the fluid's flow will continue until its viscosity increases to a point where the initial impulse is overcome by friction. Ketchup, for instance, is a thixotropic fluid that becomes increasingly less viscous due to the application of a vibratory force such that even when the vibratory force applied to a ketchup container ceases the ketchup, once moving, will continue to flow.

The Applicants contend that one of skill in the art would have interpreted the cement mixture of Constantz to be a thixotropic fluid. Accordingly, one of skill in the art would expect the calcium phosphate cement to act like a thixotropic fluid and become

less viscous in response to vibration in a time dependent manner. Therefore, contrary to the assertion by the Office, one of skill in the art, in view of the thixotropic aspect of the calcium phosphate cement disclosed in Constantz, would expect the flow of the cement mixture to continue, even after an applied vibratory force is removed.

Hence, because one of skill in the art would understand Constantz to teach, or at least suggest, that the penetration of the cement into the target bone site continues after the cessation of vibration, the conclusion by the Office upon which the rejections have been made is incorrect.

In fact, the methods disclosed in Constantz do not inherently necessitate that when the driving force for the cement delivery is removed, the flow of cement simultaneously ceases with the cessation of the driving force.

Therefore, Constantz is deficient in that it does not teach or suggest that penetration of the cement into the target bone site stops simultaneously with the cessation of vibration. As Sproul is cited solely for its disclosure of aspiration during vertebroplasty it fails to remedy the deficiencies of Constantz.

In view of the above, a *prima facie* case of obviousness has not been established because the combination of Constantz and Sproul fail to teach or suggests every element of Claims 1-2, 6-9, 11, 31-34, 36-41 and 43-45, and the Applicants respectfully request the 35 U.S.C. § 103(a) rejection be withdrawn.

Claims 1-2, 7-9, 11, 31-41 and 43-45 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Rabiner *et al.* (USPN 6,832,988).

As set forth above, an element of Claims 1, 11 and 36 is delivering a flowable cement composition to a target bone site by the application of vibration in a manner

such that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration. As described above, the Applicants contend that Constantz is deficient in that it does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops simultaneously with the cessation of vibration. As Rabiner is cited solely for its alleged disclosure of a vibratory element holder it fails to remedy the deficiencies of Constantz.

Accordingly, a *prima facie* case of obviousness has not been established because the recited combination fails to teach every element of the rejected claims. Therefore, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 1-2, 7-9, 11, 31-41 and 43-45 be withdrawn.

Claim 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* and Rabiner *et al.* in view of Sproul. Claim 6 depends from Claim 1. As set forth above, an element of Claim 1 is delivering a flowable cement composition to a target bone site by the application of vibration in a manner such that the penetration of the cement into the target bone site stops simultaneously with the cessation of vibration. As described above, the Applicants contend that Constantz is deficient in that it does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops simultaneously with the cessation of vibration. As Rabiner is cited solely for its alleged disclosure of a vibratory element holder and Sproul is cited solely for its disclosure of maceration and aspiration of soft tissue both Rabiner and Sproul fail to remedy the deficiencies of Constantz.

Accordingly, a *prima facie* case of obviousness has not been established because the recited combination fails to teach every element of Claim 6. Therefore, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 6 be withdrawn.

New Claims 46 and 47 are patentable for at least reasons provided above.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SKEL-012.

Respectfully submitted,
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Date: 10.18.06

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